#### **EXHIBIT JJ**



November 5, 2013

#### By Email

Thomas P. Cartmell, Esquire Wagstaff & Cartmell, LLP 4740 Grand Avenue, Suite 300 Kansas City, MO 64112

Re: In re Ethicon, Inc. MDL

Dear Tom:

Please accept this letter in response to your letter of late Friday afternoon, November 1, 2013, requesting information by Monday, November 4, 2013. As you know, by letter dated October 11, 2013, from Maha Kabbash, we provided an extensive explanation of the efforts undertaken to respond to inquiries relating to these issues. That communication and others outlined the efforts we recently have taken, including, but not limited to, the additional information we have identified relating to contract and payments with consultants such as Professor Ulmsten, Professor Nilsson and Professor Falconer. Below are specific responses to the numbered items in your November 1, 2013 letter.

1. Any and all documents, including the supply agreement between Ethicon in Scandinavia or elsewhere in the EU (not sure if the local entity who was supplying was Ethicon Scotland or elsewhere) and Medscand or Ulmsten or others, related to the IVS that Ulmsten and others were using during the years 1994 and 1997, as Angelini testified. This would obviously include all of the manufacturing documents, specs, etc. related to the supply of the mesh during that time.

As we have previously communicated, we have had discussions with numerous individuals, including: (1) Axel Arnaud; (2) the former Director of New Business Development ("NBD") at Gynecare France who negotiated the 1997 Licensing Agreement (who left the company about ten years ago), and (3) a former employee of the Ethicon entity in Edinburgh (which is now closed) and the J&J entity in Brussels (who worked on setting up the quality processes at Medscand in the late 1990's to enable TVT to be CE marked for sale in Europe). None of them recalls that there was a supply agreement between Ethicon and Medscand for the supply of mesh before the 1997 License Agreement was implemented. To the contrary, the former Edinburgh employee indicated that it would have been very unlikely that such an agreement would have existed, because at that time, all Ethicon mesh distributed in all of Europe was being sold through Ethicon Edinburgh, and that entity was not selling mesh directly to

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doctors or hospitals, but rather through distributors. Further, as we understand it, Medscand had pre-existing relationships with medical device distributors in Europe due to the sale and distribution of other medical device products with which Ethicon had no involvement. We continue to investigate this issue through leads we have been able to identify to attempt to ascertain information about how Medscand procured mesh for use in the TVT Device prior to the implementation of the 1997 Licensing Agreement, but to date we have not identified the existence of any such supply agreement.

I believe we previously communicated in response to your email dated October 22, 2013 to William Gage regarding Ms. Angelini's deposition testimony that the construction of the Prolene mesh used in Gynecare TVT was changed prior to the 1998 launch of the product in the United States. As William has indicated to you in telephone conferences in September, Ms. Angelini believes that portion of her testimony was mistaken, and she intends to correct her testimony at the continuation of her deposition in November. As you are aware, other witnesses have testified that no such change occurred, and we refer below to the bates numbers of documents that support this. These documents are referenced as examples only and are not intended to be an exclusive list.

ETH.MESH.01816990 ETH.MESH.09275943 ETH.MESH.09264884 ETH.MESH.09263410-ETH.MESH.09263411 ETH.MESH.02181293-ETH.MESH.02181294 ETH.MESH.00862321 ETH.MESH.09274188-ETH.MESH.09274193 ETH.MESH.02265320-ETH.MESH.02265327 ETH.MESH.01218446-ETH.MESH.01218449 ETH.MESH.02219202-ETH.MESH.02219210

We further note that, to the extent that Ms. Angelini provided this mistaken testimony on this issue or speculation as to the existence of a supply agreement for the mesh used by MedScand, it was in her capacity as a fact witness, as the subject of the supply of mesh and mesh construction of Gynecare TVT are not matters on which she was designated as a corporate representative.

Understanding that that it is our current belief, supported by our extensive investigation, that the mesh used in TVT never changed, in an effort to be as responsive as possible, we have accelerated attempts to ascertain the scope of manufacturing specifications that would apply generally to Ethicon's Prolene revision one, old construction mesh as would have been in place during the periods of time from 1994 through 1997, whether those documents still exist, whether they have been produced already and, if not, and how we can best provide relevant and responsive information to plaintiffs in this regard.

## 2. Any and all documents related to the CE mark obtained for the TVT in the EU including all submissions to regulatory agencies or from regulatory agencies or simply any and all correspondence to or from regulatory agencies related to the TVT.

Preliminarily, we would note that TVT classic is a Class IIB product. The rules and regulations under the Medical Device Directive, as applicable over time, apply to these products in connection with CE marks. Class IIB products do not require pre-market approval submissions to either a regulatory agency or to a Notified Body. Defendants have produced the Design History Files and Technical File for the TVT product for the period of time that the legal manufacturer of the product was Ethicon Sarl. These documents go back to 2002. These are the files maintained in connection with the MDD requirements. We are making additional efforts to confirm the completeness of these materials and will produce additional documents, if any, we locate connection with that effort.

Upon information and belief, for the period of time between 1999 and 2002, the TVT product was CE marked under the entity Johnson & Johnson International in Belgium and the notified body involved most likely was TUV Product Services CE 0123.

Additionally, documents related to the Technical File that may have existed in earlier time frames were recently located through Ethicon's affiliate in Germany, many of which appear to have similar information to the Technical Files and other documents previously produced. Those documents have been collected, but still are being processed for production.

Upon information and belief, the Notified Body used by Medscand for the TVT product prior to 1999 was CE0543 Presafe Denmark A/S, Tuborg Parkvej 8, DK-2900 Hellerup, Country: Denmark.

Additional documents related to the product recently were identified through Ethicon's affiliate in Scotland. Those documents have been collected, but still are being processed for production.

Finally, as you are aware, the issue of OUS regulatory documents has been the subject of motion practice and Ethicon is in the process of collecting regulatory materials from countries identified by plaintiffs. The list of countries included a number of EU countries and we will produce additional documents filed in connection with the CE mark, if any, pertaining to TVT for those countries as they are collected.

#### 3. Any and all documents related to the CE mark obtained for the IVS device for which Ethicon was supplying mesh or any other component parts.

To date, our inquiry in this regard has not identified any evidence of the existence of a CE mark for the TVT product prior to the execution of the 1997 Licensing Agreement. We continue to investigate possible leads and sources to identify information in Ethicon's possession

about how and where the product was sold and distributed by Medscand prior to Ethicon's involvement. See the response to No. 2, above, regarding submissions to regulatory agencies.

4. Any and all patient level data, protocols, study reports, correspondence or documents related to any study in the EU involving the IVS device or the TVT device between the years 1993 and 1999.

We have discussed this issue with Laura Angelini, Axel Arnaud, the former NBD director at Gynecare France referenced above, and the former Edinburgh employee referenced above. None of them has any recollection that the company received such information in the years surrounding the execution of the Licensing Agreement, as the company did not sponsor those trials and therefore did not own the information.

As also has been previously communicated, Ethicon has been able to identify one binder of what appears to be patient level data from a Scandinavian study. It is not clear to us at this time what the time frame is from this information. This binder of documents was referenced in an email chain circa 2005 (Exhibit 410 - 6/4/13), relating to a pallet of twelve cases of Medscand materials that were in the possession of Cooper Surgical around the time it purchased Medscand. The documents in this binder appear to be in Swedish and appear to involve IVS MED PROLENE SLINGA MULTICENTERSTUDIE at Vaxjo center and they reference (patiennummer 1 - 30). The documents from the binder have been collected and processed, but due to the Swedish language content, review is not yet complete to enable production. Based upon our investigation with Ethicon, it appears that the other contents of this case, except for the binder described above, were destroyed in the Secur-Archiv fire that occurred in Lausanne, Switzerland that began on September 25, 2009.

The remaining 11 cases of documents, seven of which purportedly contained product retains, and four of which purportedly contained lot documentation, are not in Ethicon's possession. To the best of our current understanding, those cases had been in a storage facility in Sweden until early 2006, at which time they were disposed of, as they no longer served any business purpose.

As we have communicated previously, we remain unaware of other sources to search for clinical information from the Ulmsten/Scandinavian trials, other than what has already been produced and marked in depositions – the published studies and the interim analysis of the Scandinavian study prepared by Medscand in 1997 and signed by Dr. Margareta Eriksson.

If additional clinical information related to the Scandinavian studies is located as we investigate other issues, we will make you aware of it promptly.

# 5. The shareholders agreement dated February 12, 1997 among Jan Johansson, Professor Ulf Ulmsten, and Dr. Nils Stormby, the amendment dated March 6, 1998, and any other amendments thereto, as well as any other Medscand shareholder agreements in Ethicon's or Johnson & Johnson's possession.

We have conducted a diligent inquiry and produced non-privileged TVT-related due diligence files in the possession of Ethicon Somerville. These were primarily located in Production 157, and identified by Bates ranges among the documents listed in Section 6 of Mr. Watson's September 10 correspondence, and in William Gage's email to you dated September 26, 2013. We have ascertained that we are in possession of a document entitled "Shareholder Agreement" identifying the Company as "Medscand Medical Aktieolag" and the parties as Medscand Aktiebolag, Ulf Ulmsten and Jan Johansson, bearing a date of February 12, 1997. The document is not signed. We are in possession of a document entitled "Supplement to Shareholders' Agreement, identifying the company as "Medscand Medical AB' and the parties as Medscand AB, Ulf ULmsten and Jan Johansson. The document has a date of March 6, 1998. It is not signed. These documents are in the process of production. If necessary, we can try to provide copies of these documents outside of the ESI protocol in order to get them to you more quickly.

### 6. The Device Master Record for the TVT Retropubic device created and maintained by Medscand Medical.

This request seeks documents that had not previously been specified in detail. Upon receipt of your November 1, 2013 letter identifying this information as a specific area of interest, we began a targeted investigation to obtain responsive information. As you know, a Device Master Record ("DMR") is a collection of documents maintained for FDA compliance purposes. Medscand never marketed the TVT product in the United States. We are attempting to ascertain whether a DMR was ever created during time frames when Medscand had responsibility for manufacture of the TVT product after the implementation of the 1997 Licensing Agreement and if so, whether those documents exist and are in the possession of Ethicon.

#### 7. Revisions 1-6 of the TVT-2 Preventia Risk analysis document. Revision 7 of this document can be found at: eth.mesh.06696465-06696474.

We have been able to locate Revision 5 of the TVT-2 Preventia Risk Analysis. It was released in production 96 at Bates Range ETH.MESH.07295614-ETH.MESH.0729522.

Any previous versions of this document likely would have been in the possession of Medscand. We have not been able to locate any earlier versions, but if they are located, we will provide them to you as quickly as possible.

In summary, we have made every reasonable effort to produce documents related to the issues raised in advance of the upcoming Laura Angelini deposition scheduled for

November 14 and 15, 2013. Given the fact that our searches have been conducted at ex-US entities, involving documents spanning over a decade that may be located in files maintained outside of the affiliates' premises – if they exist at all – we may not have been able to locate some of the documents prior to the deposition despite our best efforts.

Please do not hesitate to reach out to us to discuss these issues further.

Sincerely,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

Benjamin M. Watson

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BMW:fsw

cc: Bryan Aylstock, Esq. Renee Baggett, Esq.

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